

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)

180/157/2/2

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on June 29, 2009
 Signature Belinda Perkins

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Application Number

10/661,977

Filed

September 11, 2003

First Named Inventor

Benjamin L. Vigilanti

Art Unit

3737

Examiner

Elmer M. Chao

Applicant requests review of the third rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).

Note: No more than five (5) pages may be provided.

I am the

- ☐ applicant/inventor.
☐ assignee of record of the entire interest.
 See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
 (Form PTO/SB/96)

☒ attorney or agent of record. 39,395
 Registration number _____

☐ attorney or agent acting under 37 CFR 1.34.
 Registration number if acting under 37 CFR 1.34 _____

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06/29/2009
 Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☒ *Total of 1 forms are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Benjamin L. Viglianti

Group Art Unit: 3737

Serial No.: 10/661,977

Examiner: Chao, Elmer M.

Filed: September 11, 2003

Docket No.: 180/157/2/2

Confirmation No.: 8988

For: COMPOUNDS AND METHODS FOR BLOOD POOL IDENTIFICATION, DRUG
DISTRIBUTION, QUANTIFICATION, AND DRUG RELEASE VERIFICATION

APPLICANTS' STATEMENT IN SUPPORT OF THE
PRE-APPEAL BRIEF REQUEST FOR REVIEW

INTRODUCTION

Claims 8-34, 36-40 and 42-47 are pending in U.S. Patent Application Serial No. 10/661,977. All pending claims have been rejected on one or more bases as presented in the Official Action dated March 27, 2009 (hereinafter the "Official Action"). Applicants respectfully submit that none of the rejections presented in the Official Action are supported by the references cited by the United States Patent and Trademark Office (hereinafter the "Patent Office"), as set forth in more detail hereinbelow.

REMARKS

The 102(b) Rejection over Lang

Claims 42 and 43 have been rejected under 35 USC § 102(b) as being anticipated by PCT Published Patent Application No. WO98/44910 to Lang (hereinafter "Lang"). Applicants respectfully submit that the rejection suffers from the following errors:

- (1) Lang does not disclose "an envirosensitive liposome" as recited in claim 42.

As admitted by the Patent Office at page 4 of the Official Action, Lang, at best, teaches a non-sensitive liposome.

- (2) Lang does not disclose "wherein the liposome composition has the ability to remain in the subject's blood stream for a protracted period of time

without being recognized by the subject's reticuloendothelial system" as recited in claim 43.

By the Patent Office's own admission, Lang does not teach this element. See, e.g., page 6 of the instant Official Action.

- (3) Lang does not disclose a step of monitoring or detecting in "real time" as recited in claims 42 and 43.

By the Patent Office's own admission, Lang does not teach monitoring of the compound in real time. See, e.g., page 8 of the Final Official Action of June 10, 2008, and pages 3 and 4 of the instant Official Action. The Conference Panel is also respectfully directed to page 15 of Amendment B, filed February 27, 2009 (hereinafter "Amendment B").

- (4) Lang does not teach "monitoring release of the contents of the liposome at the desired site by monitoring an increase in the presence of the contrast agent released from the liposome at the desired site as the contents of the liposome are being released at the desired site", as recited in claim 42.

In the instant Official Action the Patent Office contends that Lang teaches this element at page 16, lines 13-15. Applicants respectfully disagree. In marked contrast to the instant claims, the referenced portion of Lang teaches the co-injection of two separate liposomes. Further, in contrast to the assertion by the Patent Office, the selected portion of Lang makes no mention of monitoring release of the contents of the liposome at the desired site by monitoring an increase in the presence of the contrast agent released from the liposome at the desired site as the contents of the liposome are being released at the desired site. Rather, Lang, at best, monitors the accumulation of the liposomes carrying the contrast agent. Thus, Lang, at best, merely assumes the release of the contents of the liposome with no verification of the release and therefore suffers from the very problem overcome by the presently disclosed and claimed subject matter. For further details the Conference Panel is respectfully directed to pages 15-22 of Amendment B.

Summarizing points (1), (2), (3) and (4), Lang does not disclose each and every element of claims 42 and 43, and thus does not support a rejection under 35 U.S.C. § 102(b).

The 103(a) Rejection over Lang in view of Unger '935

Claims 19, 20, 26-28, 42, 43 and 47 have been rejected under 35 USC §103(a) upon the contention that the claims are unpatentable over Lang in view of US Patent No. 5,542,935 to Unger (hereinafter "Unger '935"). Applicants respectfully submit that the rejection suffers from the following errors:

- (1) Regarding claims 42 and 43, Unger '935 fails to compensate for the above-noted deficiencies in Lang.

The Conference Panel is respectfully directed to pages 27-31 of Amendment B. These pages detail how the cited combination fails to teach or suggest each and every element of the claims, including the "real time" element. In the instant Official Action the Patent Office contends that the temporally spaced imaging of Lang does not preclude real time imaging. Applicants respectfully disagree. As discussed at page 21 of Amendment B, the method of Lang required 24 hours post injection to develop statistically significant enhancement of tumor tissue due to the rate of accumulation of the liposomes. Thus, real time imaging is not believed to be possible using the method of Lang. Substituting the imaging method of Unger '935 would not cure this deficiency in Lang. As such, in contrast to the Patent Office's assertion, it is believed that the method of Lang does preclude real time imaging.

- (2) Regarding claims 19, 20, 26-28, 43 and 47, applicants respectfully submit that neither Lang nor Unger '935 teach a method of detecting an *in vivo* blood pool.

Specifically, Lang and Unger '935, alone or in combination, fail to teach a method to detect an *in vivo* blood pool by administering a liposome composition to a subject, generating a magnetic resonance image and detecting the presence of an *in vivo* blood pool by analyzing the magnetic resonance image. Additionally, Unger '935 teach against the use of MRI and employs gaseous precursor-filled microspheres, not liposomes as presently claimed. The Conference Panel is respectfully directed to pages 27-31 of Amendment B for further details.

The 103(a) Rejection over Lang, Unger '935 and Fenn

Claims 8, 12, 13, 15-18, 22-25, 29-31, 33, 34, 44 and 46 have been rejected under 35 USC §103(a) upon the contention that the claims are unpatentable over Lang in view of Unger '935 and further in view of U.S. Patent No. 5,810,888 to Fenn (hereinafter "Fenn"). Applicants respectfully submit that the rejection suffers from the following errors:

- (1) Fenn does not cure the above-noted deficiencies in Lang and Unger '935.

The Conference Panel is respectfully directed to pages 15-23 of Amendment B regarding the failure of Fenn to cure the deficiencies in Lang. In particular, Fenn does not teach or suggest a method of monitoring drug distribution or accumulation wherein the release of the drug from the liposome is verified, at the desired site, and as the contents are being released from the liposome. Fenn merely assumes that the contents of the liposome are released. Thus, Fenn does not compensate for the deficiencies in Lang and Unger '935.

The 103(a) Rejection over Lang, Unger '935, Fenn and Unger '319

Claims 9-11, 14, 24, 32, 36-40 and 45 have been rejected under 35 USC §103(a) upon the contention that the claims are unpatentable over Lang in view of Unger '935, further in view of Fenn, and further in view of US Patent No. 5,149,319 to Unger (hereinafter "Unger '319"). Applicants respectfully submit that the rejection suffers from the following errors:

- (1) Unger '319 does not cure the above-noted deficiencies in Lang, Unger '935 and Fenn.

The Conference Panel is respectfully directed to pages 23-25 of Amendment B regarding the failure of Unger '319 to cure the deficiencies in Lang and Fenn. Unger '319 at best teaches a method of heat treating biological tissues and fluids using a hyperthermic potentiator in combination with ultrasound. Unger '319 does not disclose the claimed method wherein the monitoring comprises monitoring release of the contents of the liposome at the desired site by monitoring an increase in the presence of the contrast agent exterior to the liposome and at the desired site as the contents of the liposome are being released at the desired site, and therefore does not compensate for the deficiencies of Lang and/or Fenn.

The 103(a) Rejection over Lang, Unger '935 and Gamble

Claim 21 has been rejected under 35 USC §103(a) as being unpatentable over Lang, in view of Unger '935, and further in view of US Patent No. 4,728,575 to Gamble (hereinafter "Gamble"). The rejection suffers from the following errors:

(1) Gamble does not cure the noted deficiencies in Lang and Unger '935.

Gamble does not disclose monitoring an increase in the presence of the contrast agent exterior to the liposome and at the desired site as the contents of the liposome are being released at the desired site, and therefore does not compensate for the deficiencies of Lang and Unger '935.

SUMMARY

The Patent Office has not presented a *prima facie* case of anticipation of claims 42 and 43 over Lang because Lang does not disclose: 1) "an envirosensitive liposome"; 2) "wherein the liposome composition has the ability to remain in the subject's blood stream for a protracted period of time without being recognized by the subject's reticuloendothelial system"; 3) "real time"; and 4) "monitoring release of the contents of the liposome at the desired site by monitoring an increase in the presence of the contrast agent released from the liposome at the desired site as the contents of the liposome are being released at the desired site", as recited in the claims. The Patent Office has not presented a *prima facie* case of obviousness of claims 8-34, 36-40 and 42-47 over Lang in combination with any of Unger '935, Fenn, Unger '319 and Gamble because none of these references cure the deficiencies in Lang, and the proposed combinations fail to teach or suggest each and every element of the claims.

Accordingly, applicants respectfully submit that claims 8-34, 36-40 and 42-47 are in condition for allowance. Applicants respectfully request a Notice of Allowance for claims 8-34, 36-40 and 42-47.

Respectfully submitted,
JENKINS, WILSON, TAYLOR & HUNT, P.A.

Date: 06/29/2009

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